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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael H. Qvist

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,243	QVIST, MICHAEL H.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9, and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-10 are currently pending and are the subject of this Office Action. Claims 1, 2, 9, and 10 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Election/Restrictions

In response to the species election requirement, applicant has elected a protease-controlling agent as the species of therapeutic ingredient in the reply filed on Sep. 15, 2008. Paragraphs [0033]-[0039] of the instant specification list the various classes of therapeutic ingredients recited in claims 2-7 separately as non-overlapping species. Thus, it is clear that these species represent distinct embodiments of the invention. Therefore, claims 3-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claim 8, which depends from claim 1, recites the limitation "the proteolytic enzyme" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim as no proteolytic enzyme is recited in claim 1. It appears that this claim should depend from claim 7, which recites a proteolytic enzyme. However, since claim 7 is drawn to a nonelected species, claim 8 has been withdrawn as well. Election was made **without** traverse.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Oct. 8, 2004, the filing date of PCT application PCT/DK04/00690 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Danish application was filed with the USPTO on Apr. 10, 2006.

Abstract

The abstract of the disclosure is objected to because the word "comprising" in line 3 of the abstract should be "comprise".

Specification

The title of the invention is not adequately descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. At a minimum, the title should make reference to the presence of liposomes and absorbent material, which are the critical components in the claimed dressings.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim elements "exudates handling means" and "releasing means" are means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. The instant specification does not clearly define exudates handling means or releasing means and it is not clear what the intended exudates handling or releasing means actually is/are.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 6,264,979; Issued Jul. 24, 2001) (hereinafter Svedman).

1. Svedman discloses transdermal devices intended to be applied to de-epithelialized skin (i.e. wound dressings) (abstract; column 2, lines 8-11 and 48-49; column 3, lines 55-60). The devices taught by Svedman comprise an absorbent layer (Figure 16, element 68; column 11, lines 55-58), which is an exudates handling means as defined in paragraphs [0018] and [0023] of the instant specification. Svedman also teaches that the active agent is protected from attack by proteolytic enzymes exuding from the wound by encapsulating the active agent in liposomes (column 6, lines 41-44; claim 17). The instant specification does not clearly define releasing means, but makes

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reference to the fact that release may be induced by the action of phospholipases expressed by various bacteria present in the wound (paragraph [0032]). In particular, phospholipase C is discussed as being expressed by the types of bacteria that commonly cause infections in wounds and as being able to effect release of the active agent from liposomes via hydrolysis of the glycerol-phosphate linkage in various phosphatides (paragraph [0032]).

2. Thus, because liposomes are cleavable by various phospholipases produced by microorganisms in a wound they qualify as possessing a "releasing means". It is noted that paragraph [0030] of the instant specification states that the wound constituent that triggers the release of the active agent from the liposomes may be a compound produced by microorganisms in the wound (i.e. phospholipases). Svedman teaches that the wound exudate will include bacteria, whole cells, cellular debris, and enzymes (column 2, lines 53-54). Therefore, the devices taught by Svedman possess each limitation of instant claim 1 and anticipate this claim.

3. Svedman teaches the use of protease-controlling agents such as protease inhibitors (column 5, lines 56-60; column 6, lines 3-6, 11-14, and 20-34), reading on instant claim 2.

4. The wound constituent may be a lipase that is produced from wound-dwelling bacteria, which is a biological constituent that would be present in a chronic wound, reading on instant claim 9. Furthermore, as taught by Svedman, the wound exudate would contain bacteria, and thus their associated lipases (i.e. the wound constituent), reading on instant claim 10.

Claim 1, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Martineau *et al.* (WO 01/15750; Published Mar. 8, 2001; Reference AO on IDS dated Dec. 18, 2006) (hereinafter Martineau *et al.*).

5. Martineau *et al.* disclose wound dressings comprising hydrogels (i.e. a wound exudates handling means as defined in paragraph [0023] of the instant specification) and therapeutic agents contained in liposomes (abstract; page 5, last paragraph). As discussed above, by virtue of the chemical structures, liposomes inherently possess releasing means as defined in the instant specification (paragraph [0032]) since the lipids can be cleaved by lipases. Since lipases produced by wound-dwelling bacteria are wound constituents as defined in paragraph [0030] of the instant specification, Martineau *et al.* read on instant claim 1.

6. Since the wound constituent may be a lipase that is produced from wound-dwelling bacteria, it is a biological constituent that would be present in a chronic wound, reading on instant claim 9. Furthermore, since the wound exudate would contain bacteria and their associated lipase, the wound constituent is present in the wound exudate, reading on instant claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martineau *et al.* in view of Cullen *et al.* (WO 03/047643; Published Jun. 12, 2003; Reference Reference AN on IDS dated Dec. 18, 2006) (hereinafter Cullen *et al.*).

7. Martineau *et al.* disclose the wound dressings of instant claim 1 as applied above. Martineau *et al.* teach that any active agent that can be compounded into liposomes can be used in their invention (page 6, 4th paragraph) and also teach the use of multiple therapeutics and various combinations thereof (page 6, last paragraph). Martineau *et al.* do not teach the use of protease-controlling agents in their wound dressings.

8. However, Cullen *et al.* disclose absorbent wound dressings comprising therapeutic agents and protease inhibitors (abstract). Cullen *et al.* teach that wound fluids often have high levels of proteases (paragraph [0014]) and that proteases are, in part, responsible for the generation of pain (paragraph [0007]). In light of these teachings, one of ordinary skill in the art at the time the invention was made would have been motivated to include protease inhibitors (i.e. protease-controlling agents) in the wound dressings taught by Martineau *et al.*, with the expectation of reducing the pain associated with the wound. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include protease inhibitors along with other therapeutic agents in the dressings of Martineau *et al.*, reading on claim 2.

9. It is noted that a reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from

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the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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KSO

/Andrew D Kosar/

Primary Examiner, Art Unit 1654